

General Guidelines for Developing Assent Forms for Participation in CDC Research Activities

The federal regulations that govern the protection of human subjects involved in research state that adequate provisions must be made for soliciting the assent of children when in the judgment of the IRB the children are capable of providing assent and for soliciting the permission of their parents or guardians (45 CFR 46.407 and .408). Generally, CDC IRBs require that the assent of a minor child be sought when the child is seven years of age or older, unless the child's decision-making capacity is impaired.

For children 7 to 11 years of age, the assent form should be simple enough for the child to understand what he/she is agreeing to do. In general, it should briefly explain in basic terms:

- that they are being asked to participate in a research study;
- the purpose of the study;
- an estimate of how much time is involved in participating;
- what will happen to them if they agree to participate (e.g., "draw some blood");
- the foreseeable risks and/or discomfort and any benefits they may experience (should stress the immediate risks and/or discomfort and benefits, rather than future or theoretical possibilities);
- that they should ask their parents or the doctor or researcher any questions they have about participating;
- that their participation is voluntary, and that they may discontinue participation at any time;
- that their father/mother/guardian has said that it's all right for them to participate.

For adolescents between the ages of 15 and 17, the assent form should closely follow the consent form used for consenting adult participants. Please see 45 CFR 46.116(a) for the basic required elements of informed consent that should be included in adult and adolescent (ages 15 to 17) consent forms.

For children between the ages of 12 and 14, investigators should use their judgment in deciding which of the required elements of informed consent (outlined in 45 CFR 46.116(a)) would be most appropriate for their study population.